IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

HY-KO PRODUCTS COMPANY, *et al*.,	)	**CASE NO. 5:08cv1961**
	)	
Plaintiffs,	)	
	)	**JUDGE DOWD**
v.	)	
	)	
THE HILLMAN GROUP, INC.,	)	
	)	
Defendant.	)	**SURREPLY IN OPPOSITION TO HILLMAN'S MOTION TO DISMISS HY-KO'S DECLARATORY JUDGMENT CLAIMS RELATING TO THE '747 PATENT**
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Hy-Ko Products Company and Aurora Properties Holding Co., LLC (collectively, "Hy-Ko") submit this brief surreply in opposition to Hillman's Motion to Dismiss Hy-Ko's Declaratory Judgment Claims Relating to the '747 Patent. Hillman's mischaracterization of the term "beta version" and reliance on exceptions articulated in pharmaceutical products law is entirely misplaced.

Hillman provides an uncited definition of "beta version" in its brief defining a "beta" product as one that is, "not made or sold in a commercial capacity." (Hillman's Reply at 2.) It is common, however, for companies to sell beta versions of products commercially and for those companies to be subject to patent infringement lawsuits for those products. Since, 35 U.S.C. § 271 makes no distinction as to the quality of a commercial sale[1], or as to the use of a patented invention, merely that a commercial sale or use exists, a real and justiciable controversy

[1] 35 U.S.C. § 271(a) states in pertinent part, "whoever without authority **makes**, **uses**, offers to sell, or sells any patented invention, within the United States, or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." (Emphasis added.)

also exists regarding future infringement claims brought by Hillman for use of Hy-Ko's machines and its commercial sales.

Hillman relies upon two pharmaceutical patent infringement cases where the standard for infringement is modified by the provisions of the Hatch-Waxman Act. First Hillman asserts that in *MedImmune v. Genentech, Inc*., 535 F. Supp. 2d 1000, 1008-10 (C.D. Cal. 2008), the court found a covenant not to sue "to be sufficient to remove declaratory judgment jurisdiction despite the covenant not covering 'the next generation' of the product at issue even when this 'next generation' had completed clinical trials." (Hillman's Reply at 2.) This analysis is simply inapt.

In *MedImmune*, the issue involved a partial covenant not to sue offered *after* a Markman hearing and following the release of a new *pharmaceutical* product by MedImmune called NuMax. MedImmune had consistently maintained that the product was not part of the present suit because the product was in clinical trials. Critically, the product was expressly not infringing the subject patent because it was exempted by 35 U.S.C. § 271(e)(1) which states in pertinent part:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs or veterinary biological products.

This statute, part of the 1984 Hatch-Waxman Act, provides a very particular "safe harbor" from claims of patent infringement based on activities *related to the pursuit of FDA approval of drug products*. The *MedImmune* Court further noted that NuMax was more than *five years away from market* at the time MedImmune filed its complaint and was still *10 months*

away from FDA approval at the time the court was considering the covenant not to sue, a date that would fall after the trial scheduled in the action. *MedImmune*, 535 F. Supp. 2d 1000 at 1010 (emphasis added).

Here, obviously there are no "clinical trials," and Hy-Ko has incontestably fielded its technology into a Walmart store in Macedonia, Ohio where it is currently being used to cut keys offered for sale to consumers. The machine is in *commercial* use and plainly not in the "pipeline," so the MedImmune Court's rationale that the NuMax product would not be commercially sold until after the end of the infringement trial is not applicable. It almost goes without saying that Hy-Ko's key-cutting machine is not a drug product protected by Hatch-Waxman, and there is no impending future approval, as in *MedImmune*, to be obtained by Hy-Ko from any governmental agency such as the FDA.

Second, and similarly inapplicable, is the second pharmaceutical case cited by Hillman, *Amgen, Inc. v. Ariad Pharmaceuticals, Inc.*, 577 F. Supp. 2d 702 (D. Del. 2008). *Amgen* involved numerous drugs that were indisputably in the "pipeline" and at various stages of Phase I, II, and III clinical trials[2]. *Amgen*, 577 F. Supp. 2d at 710. The *Amgen* court's case citations and parentheticals show convincingly the difference between *Amgen* and this case. The Court cited: "*See Amana Refrigeration, Inc. v. Quadlux, Inc.,* 172 F.3d 852, 855 (Fed. Cir. 1999) (rejecting argument based on pipeline products stating 'an actual controversy cannot be based on a fear of litigation over **future products**'); *see also Vision Biosystems (USA) Trading, Inc. v. Ventana Medical Systems, Inc.,* No. Civ.A. 03-10391-GAO, 2004 U.S. Dist. LEXIS 21449, 2004 WL 2387284, *11 (D. Mass. Sept. 30, 2004) (covenant not to sue need not cover **hypothetical,**

[2] A "clinical trial" is controlled test of a new drug that is used to gather safety and efficacy data to support application to the Food and Drug Administration to market a pharmaceutical product.

future products); *Taylor Brands, LLC v. SOG Specialty Knives, Inc.,* No. 2:06-CV-16, 2008 U.S. Dist. LEXIS 11236, 2008 WL 413625 (E.D. Tenn. Feb. 13, 2008) (Report and Recommendation) ('**[N]ebulous future events** which may or may not occur will not defeat a Covenant Not To Sue, assuming of course that the covenant's language accomplishes its avowed purpose.')." (Emphasis added.).

In all of the examples cited by the *Amgen* Court there was no actual commercial use, sale, or offers for sale of the "future" infringing products. In contrast, Hy-Ko is currently using the Completed KZA-200 Key Identification System in a Walmart store. Hy-Ko's Completed KZA-200 Key Identification System is not a "future product," and it is certainly not a "hypothetical" future product. Hy-Ko's placement of this key identification system into commercial use is also no "nebulous future event." The Completed KZA-200 Key Identification System is in full operation now in a Walmart store within a few miles of this Court.

For the reasons above, as well as those set forth in its Opposition to Hillman's Motion to Dismiss Hy-Ko's Declaratory Judgment Claims Relating to the '747 Patent, Hy-Ko respectfully requests that this Court deny Hillman's Motion to Dismiss.

Respectfully Submitted,

/s/ Gary L. Walters
STEVEN S. KAUFMAN (0016662)
Steven.Kaufman@ThompsonHine.com
O. JUDSON SCHEAF, III (0040285)
Judson.Scheaf@ThompsonHine.com
MEGAN D. DORTENZO (0079047)
Megan.Dortenzo@ThompsonHine.com
GARY L. WALTERS (0071572)
Gary.Walters@ThompsonHine.com
HOLLY H. ARMSTRONG (0084054)
Holly.Armstrong@ThompsonHine.com
THOMPSON HINE LLP
3900 Key Center
127 Public Square
Cleveland, OH 44114
Telephone: (216) 566-5500
Fax: (216) 566-5800

Attorneys for Plaintiffs Hy-Ko Products Company & Aurora Properties Holding Company, LLC

CERTIFICATE OF SERVICE

I certify that a copy of the foregoing Surreply in Opposition to Hillman's Motion to Dismiss Hy-Ko's Declaratory Judgment Claims Relating to the '747 Patent was electronically filed on September 15, 2009. A copy of the same will be served on counsel of record by operation of the Court's electronic filing system. Parties may access this filing through the Court's electronic filing system.

/s/ Gary L. Walters
One of the Attorneys for Hy-Ko Products Company and Aurora Properties Holding Company, LLC